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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/677,920
Applicant: Korba *et al*
Filed: October 1, 2003
TC/A.AU.: 1648
Examiner: Unassigned

Confirmation No.: 9596

Docket No.: 09128.105002 GGT1000
Customer No.: 20786
Title: Diagnostic for Long Term Response of HBV Carrier to 3TC Therapy

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

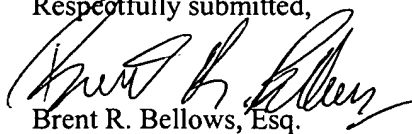
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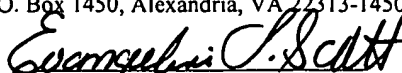
Respectfully submitted,


Brent R. Bellows, Esq.
Reg. No. 54,709

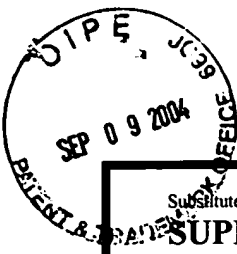
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**SUPPLEMENTAL
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet **1** of **4****Complete if Known**

Application Number	10/677,920
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Group Art Unit	1648
Examiner Name	Unassigned
Attorney Docket Number	09128.105002 GGT1000

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U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages/Relevant Figures Appear
		Number	Kind Code (if known)			
	AA	6,555,311		Locarnini <i>et al.</i>	04-29-2003	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number	Kind Code ² (if known)				
	AB	WO	97/40193	A2	Innogenetics N.V.	10-30-1997		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

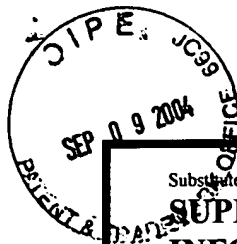
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	AC	AHMED, Si Nafa Si, et al. <i>Early detection of viral resistance by determination of hepatitis B virus polymerase mutations in patients treated by lamivudine for chronic hepatitis B.</i> Hepatology. 2000;32(5):1078-88.	
	AD	ALLEN, M.I., et al. <i>Identification and characterization of mutations in hepatitis B virus resistant to lamivudine.</i> Hepatology 1998; 27:1670-1677.	
	AE	ANDREONE, B.P et al. <i>Response to extended lamivudine treatment of HBEAG negative chronic Hepatitis B.</i> Hepatology (AASLD Abstracts). 2001; 34(4 part 2):321A, Abstract No. 598.	
	AF	BARTHOLOMEUSZ, A., Locarnini SA. <i>Mutations in the hepatitis B virus polymerase gene that are associated with resistance to famciclovir and lamivudine.</i> Int. Antiviral News 1997; 5:8;123-124.	
	AG	BARTHOLOMEW, M.M., et al. <i>Hepatitis B virus resistance to lamivudine given for recurrent infection after orthotopic liver transplantation.</i> Lancet 1997; 349:20-22.	
	AH	CHAYAMA, K., Suzuki Y, et al. <i>Emergence and take over of YMDD motif mutant hepatitis B virus during long-term lamivudine therapy and re-takeover by wild-type after cessation of therapy.</i> Hepat. 1998; 27(6):1711-1716.	
	AI	CHO, S.W., et al. <i>Reversion from precore/core promoter mutants to wild type hepatitis b virus during the course of lamivudine therapy.</i> Hepatology 2000; 32(5)1163-1169.	
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	AL	FU, L., Cheng YC. <i>Role of additional mutations outside the YMDD motif of hepatitis B virus polymerase in L(-) ddC (3TC) resistance.</i> Bioch. Pharmac 1998; 55:1567-72.	

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**SUPPLEMENTAL
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First Named Inventor	Korba <i>et al</i>
Group Art Unit	1648
Examiner Name	Unassigned
Attorney Docket Number	09128.105002 GGT1000

Sheet	2	4
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	BA	HADZIYANNIS, S.J., et al. <i>Efficacy of long-term lamivudine monotherapy in patients with Hepatitis B e antigen-negative chronic Hepatitis B</i> . Hepatology. 2000; 32:4:847-851.	
	BB	HADZIYANNIS, S.J., et al. <i>Hepatitis B e Antigen-negative chronic hepatitis B</i> . Hepatology 2001; 34: 617-624.	
	BC	HORIKITA, M., et al. <i>Differences in the entire nucleotide sequence between hepatitis B virus genomes from carriers positive for antibody to hepatitis B e antigen with and without active disease</i> . J Med Virol. 1994 Sep;44(1):96-103.	
	BD	KAO, J.H., <i>Sequence analysis of pre-S/surface and pre-core/core promoter genes of hepatitis B virus in chronic hepatitis C patients with occult HBV infection</i> . J Med Virol 2002; 68:216-220.	
	BE	KUROSAKI, M., et al. <i>Mutations in the core promoter region of hepatitis B virus in patients with chronic hepatitis B</i> . J Med Virol. 1996 Jun;49(2):115-123.	
	BF	LARAS, A., et al. <i>Conservation of HBV core promoter and precore sequences during the course of long-term lamivudine monotherapy</i> . Hepatology (AASLD Abstracts). 2001; 34(4 part 2):324A, Abstract No. 609.	
	BG	LI, J.S., et al. <i>Hepatitis B virus genotype A rarely circulates as an HBe-minus mutant: possible contribution of a single nucleotide in the precore region</i> . J Virol. 1993;67(9):5402-5410.	
	BH	LING, R., Harrison, T.J. <i>Functional analysis of mutations conferring lamivudine resistance on hepatitis B virus</i> . J Gen Virol. 1999; 80:601-606.	
	BI	LING, R., et al. <i>Selection of mutations in the hepatitis B virus polymerase during therapy of transplant recipients with lamivudine</i> . Hepatology. 1996; 24(3):711-713.	
	BJ	LOK, A.S.-F., et al. <i>Evolution of hepatitis B virus polymerase gene mutations in hepatitis B e antigen-negative patients receiving lamivudine therapy</i> . Hepatology 2000; 32:1145-1153.	
	BK	LOK, A.S.F., et al. <i>Monitoring drug resistance in chronic hepatitis B virus (HBV)-infected patients during lamivudine therapy: evaluation of performance of INNO-LiPA HBV DR assay</i> . J Clin Microbiol. 2002;40(10):3729-3734.	
	BL	NAOUMOV, N.V., et al. <i>Emergence and characterization of lamivudine resistant hepatitis B variant</i> . Hepatology 1996; 24:282A, Abstract No. 621.	
	BM	NIESTERS, H.G.M., et al. <i>Identification of a new variant in the YMDD motif of the hepatitis B virus polymerase gene selected during lamivudine therapy</i> . J Med Microbiol. 2002; 51: 695-699.	
	BN	NORDER, H. et al. <i>Complete genomes, phylogenetic relatedness and structural proteins of six strains of hepatitis B virus, four of which represent two new genotypes</i> . Virology 1994; 198:489-503.	
	BO	OGATA, N., et al. <i>Novel patterns of amino acid mutations in the hepatitis B virus polymerase in association with resistance to lamivudine therapy in Japanese patients with chronic hepatitis B</i> . J Med Virol. 1999; 59: 270-276.	

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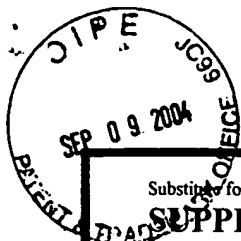
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	CA	OKAMOTO, H., et al. <i>Hepatitis B virus with mutations in the core promoter for an e antigen-negative phenotype in carriers with antibody to e antigen.</i> J Virol. 1994; 68(12):8102-10.	
	CB	PAGANIN, S., <i>Long term lamivudine monotherapy in chronic e-antigen negative HBV related liver disease: Resistance and mutation in polymerase region.</i> Hepatology (AASLD Abstracts). 2001; 34(4 part 2):630A, Abstract No. 1834.	
	CC	PAPATHEODORIDIS GV, et al. <i>Long-term lamivudine monotherapy in patients with HBEAG-negative HBV related chronic liver disease: Predictors of virological and biochemical breakthroughs.</i> Hepatology (AASLD Abstracts). 2001; 34(4 part 2):632A, Abstract No. 1839.	
	CD	PAPATHEODORIDIS, G.V., et al. <i>Course of virologic breakthroughs under long-term lamivudine in HBeAg-negative precore mutant HBV liver disease.</i> Hepatology 2002; 36:1: 219-226	
	CE	PILLAY, D., et al. <i>Mutations in the hepatitis B virus DNA polymerase associated with antiviral resistance.</i> International Antiviral News 1998; 6:9: 167-169.	
	CF	RIZZETTO, M., et al. <i>Response of pre-core mutant chronic hepatitis B infection to lamivudine.</i> Med Virol. 2000 Jul;61(3):398-402.	
	CG	RIZZETTO, M., <i>Efficacy of lamivudine in HBeAg-negative chronic hepatitis B.</i> J Med Virol. 2002;66(4):435-451.	
	CH	RODRIGUEZ-FRIAS, F., et al. <i>Hepatitis B virus infection: precore mutants and its relation to viral genotypes and core mutations.</i> Hepatology. 1995;22(6):1641-1647.	
	CI	SABLON, E., et al. <i>Early and sensitive detection of drug resistance-associated mutations in Hepatitis B-infected patients during lamivudine therapy: The Inno-LIPA HBV DR assay proves be superior to direct sequencing.</i> Hepatology (AASLD Abstracts). 2001; 34(4 part 2):321A, Abstract No. 595.	
	CJ	SALLAM, T.A., et al. <i>Two distinct types of hepatitis B virus core promoter variants in Yemeni blood donors.</i> 2002. J. Med. Virol. 68:328-34.	
	CK	STUYVER, L., et al. <i>Line probe assay for monitoring drug resistance in hepatitis B virus-infected patients during antiviral therapy.</i> J. Clin. Microbiol. 2000.38:702-707.	
	CL	STUYVER, L.J., et al. <i>Nomenclature for antiviral-resistant human hepatitis B virus mutations in the polymerase region.</i> Hepatology 2001; 33:751-757.	
	CM	TASSOPOULOS, N., et al. <i>A multicenter 3 year open study of lamivudine in HBEAG negative chronic hepatitis B (interim report of the first year).</i> Hepatology (AASLD Abstracts). 2001; 34(4 part 2):323A, Abstract No. 605.	
	CN	TIPPLES, G.A., et al. <i>Mutation in HBV RNA-dependent DNA polymerase confers resistance to lamivudine in vivo.</i> Hepatology. 1996;24(3):714-717.	

Examiner Signature		Date Considered	
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	DA	TORRESI, J., et al. <i>Restoration of replication phenotype of lamivudine-resistant hepatitis B virus mutants by compensatory changes in fingers subdomain of the viral polymerase selected as a consequence of mutations in the overlapping S gene.</i> Virology 2002; 299:88-99.	
	DB	YEH, C.-T., et al. <i>Clearance of the original hepatitis B virus YMDD-motif mutants with emergence of distinct lamivudine-resistant mutants during prolonged lamivudine therapy.</i> Hepatology. 2000;31(6):1318-1326.	
	DC	ZHANG, X., et al. <i>Detection of hepatitis B virus polymerase variations resistant to lamivudine therapy.</i> Chin Med J (Engl). 2000;113(5):455-7.	
	DD	ZOULIM, F., et al. <i>Is lamivudine effective on precore/core promoter mutants of hepatitis B virus?</i> Hepatology. 2000; 32:1172-1174.	

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